IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
Gehringer et al.	Art Unit: 3739
Appl. No: 10/533,160	Examiner: K.C. Carlson
Confirmation No: 7155	
Filed: October 12, 2005	Atty. Docket No: 37998-237519
For: PREKALLIKREIN DEPLETED PLASMA DERIVED ALBUMIN FRACTION	Customer No: 26694

Declaration under 37 C.F.R. § 1.132

Commissioner for Patents
Mail Stop Amendment
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

I, the undersigned, declare the following, based on my own knowledge, information, and belief.

1. My educational and professional background is attached as Appendix A.

2. I have reviewed the Office Action dated December 19, 2008 (the Office Action). It is my understanding that the Examiner is stating that claims 1, 2, 9, 11 and 12 are unpatentable over the Tanaka et al. references and Matejtshuk et al. in the combinations provided in the Office Action . See Office Action at pg. 3. I disagree for at least the reasons below.

3. It is my understanding that claim 12 is directed to a method of manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content consisting essentially of: (a) reconstitution of paste V (Cohn fractionation) to form a first fraction; (b) concentrating the first fraction obtained in step (a) to obtain a concentrated fraction; (c) pasteurizing the concentrated fraction obtained in step (b) for a time period of at least nine hours at a temperature of 58 °C to 65 °C to obtain a pasteurized fraction; (d) filling vials with the pasteurized fraction; and (e) incubating the vials for 10 days at 30 °C to 32 °C or for four weeks at 20 °C to 25 °C to obtain an albumin enriched fraction having a PKA content of less than 12 IU/ml.

4. One of skill in the art will see that the method in claim 12 includes the material steps of a distinct purification process from those shown in the documents cited by the Examiner. It is my understanding that this claim covers these materials steps and non-material additions to this method because of the "consisting essentially of" transition language. One of skill in the art would appreciate that the addition of a chromatographic purification step, such as those discussed to follow, into the claimed method would be considered a material addition.

5. One of the advantages of the claimed invention recited in claim 12 is that no chromatographic purification step is required. This provides substantial benefits including easier handling due to less work-load and the use of less demanding equipment. Thus, this process is more economical while it still provides a safe high-quality product. There is no need for chromatographic material such as columns and resins. Each chromatographic step requires a careful selection of loading and elution conditions, such as resin, pH, ionic strength, temperature and kind of loading/elution buffer. Additionally, a concentration step and buffer exchange is usually needed after each chromatographic step for further processing.

6. In contrast to claim 12, the Tanaka et al. (1998) reference discloses a purification process of human albumin by applying liquid chromatography to the supernatant of Cohn fraction IV. See, e.g., pg. 1385, left column. For example, Tanaka et al. use the supernatant of Cohn IV as starting material for chromatographic purification (actually applying 4 columns connected in series) and gel filtration whereas the claims use Cohn V paste (which is a precipitate derived from the Cohn IV supernatant)[1]. However, the method of claim 12 does not require a chromatographic step as Tanaka et al. teaches.

7. The second Tanaka et al. (2000) reference refers to the preparation of IgG from Cohn pastes I+II+III or II+III by means of ion exchange chromatography (performed on Q-Separose FF (anion exchange chromatography) and CM-Sepharose FF (cation exchange chromatography)) and gel filtration (Sepharyl 5-300 HR). See, e.g., the Abstract (emphasis added). Claim 12, however, is directed to a prekallikrein activator depleted plasma derived albumin fraction, which is a different product, processed from a different source, by a completely different process, than those taught by Tanaka et al. (2000).

8. Matejtschuk et al. discloses various methods for the preparation of human albumin solutions (see, e.g., fig. 1, pgs. 888-891) among which are three processes comprising at least one chromatographic step (Zenalab, CSL Albumex, Bergloff) and three processes without any chromatographic step (Hink, Cohn, Kistler & Nitschmann). The fractionation processes of Cohn and Kistler & Nitschmann purport to disclose Fraction V, filling and pasteurization but there is no indication of any incubation as the claims require or that the claimed prekallikrein activator content could be achieved using these processes. Therefore, even in view of the processes without a chromatographic step in Matejtschuk et al., this document does not teach all the features of claim 12.

[1] See, e.g., Matejtschuk et al., pg. 890, right column above "Chromatographic purification."

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 9th day of June, 2009

K. POCK 09. JUNI 2009

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1984 – 1991:	Study of chemistry at the University of Vienna
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1995 – 1997:	Ph.D. thesis at the Institute of Applied Microbiology of the University of Agriculture and Forestry, Vienna in collaboration with the Institute of Analytical Chemistry of the University of Vienna and Octapharma Vienna, entitled: "Characterization of Factor VIII using high resolution techniques"

EXPERIENCES:

1988 – 1991:	Assistant for students of biology at the chemical laboratory at the University of Vienna
1991 – 1995:	Federal Institute for Food Control and Research
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